IN THE MATTER OF \* BEFORE THE

CALLIXTUS NWAEHIRI, P.D. \* MARYLAND STATE BOARD

LICENSE NO. 10899 \* OF PHARMACY

Respondent \* Board Case Number: 05-162

#### FINAL DECISION AND ORDER

## **Procedural History**

On August 17, 2009, the Maryland Board of Pharmacy (the "Board") issued Mr. Callixtus Onigbo Nweahiri, P.D. a Notice of Intent to Revoke Pharmacist's License based upon Mr. Nwaehiri's criminal convictions in the United States District Court for the District of Maryland on counts of conspiracy to distribute controlled substances; aiding and abetting distribution of controlled substances (nearly eight million doses); aiding and abetting conspiracy to launder monetary instruments; monetary transactions with criminally derived proceeds; and filing false tax returns. Mr. Nwaehiri's business partner, Mr. Steven Sodipo, P.D. was also issued a Notice of Intent to Revoke based on his convictions for the same felonies.

A quorum of the Board held an evidentiary hearing on January 13, 2010. Mr. Nwaehiri participated telephonically from the Federal Correctional Institution in Ft. Dix, New Jersey, where he is currently incarcerated. Upon conclusion of the hearing, the same quorum of the Board convened to deliberate and voted unanimously to sanction Mr. Nwaehiri's pharmacist license for the reasons set forth in this Order.

<sup>&</sup>lt;sup>1</sup> Mr. Nwaehiri's hearing was consolidated with the hearing requested by Mr. Sodipo, who was also subject to the same disciplinary action based on the same factual allegations.

## SUMMARY OF THE EVIDENCE

#### A. Documents

The following documents were admitted into evidence:

### State's Exhibits:

Ex. 1	Maryland Board of Pharmacy Database Printout of Licensure Information
Ex. 2	Summary Suspension Order, dated 11/08/06
Ex. 2A	Order Continuing Summary Suspension, dated 1/05/07
Ex. 3	Judgment in a Criminal Case, dated 12/12/08
Ex. 4A	Notice of Intent to Revoke Pharmacist's License
Ex. 4B	Respondent's Reply to Notice of Intent to Revoke Pharmacist's License,
	dated 8/28/09;
Ex. 4C	Notice of Hearing, dated 11/5/09

# Respondent's Exhibits:<sup>2</sup>

Kespona	ent's Exhibits:
Ex. 1	Letter to Board requesting discovery, dated 8/28/09
Ex. 2	Hydrocodone prescription, #4094102, written by Dr. Stanley Mark Dratler
Ex. 3	64B8-9.014, Florida Administrative Code – Standards for Telemedicine
	Prescribing Practice, revised 9/14/03
Ex. 4	Article by Feder, Jody, Legal issues Related to Prescription Drug Sales on
	the Internet, Congressional Research Service, March 5, 2004
Ex. 5	The Federation of State Medical Boards of the United States, Inc., Model
	Guidelines for the Appropriate Use of the Internet in Medical Practice,
	2002
Ex. 6	Prescribing Guidelines in Florida, Florida State Medical Board <sup>3</sup>
Ex. 7	Article by Rubin, Melvin, Prescriptions Sent Through the Internet,
	Maryland State Board of Pharmacy Newsletter, April 2005
Ex. 8	Prescriptions for Out of State Prescribers, Clarification to Maryland State
	Roard of Pharmacy Newsletter Article, 2005

## **B.** Witnesses

## For the State:

Colin Eversley, Maryland Board of Pharmacy Investigator

## For the Respondent:

Callixtus Nwaehiri, P.D., Respondent

<sup>&</sup>lt;sup>2</sup> Mr. Nwaehiri did not provide the Board with any of his exhibits prior to the hearing. However, the Board allowed Mr. Nwaehiri 14 days from the date of the hearing to submit Exhibit 2 as it was the only exhibit not publicly available or in the Board's file. (Tr. at 69).

<sup>&</sup>lt;sup>3</sup> After considerable effort, the Board was unable to locate a publicly available document entitled *Prescribing Guidelines in Florida* written by physicians of the State Medical Board as Mr. Nwaehiri indicated during the hearing. (Tr. at 57).

#### PRE-HEARING MOTIONS

On August 28, 2009, Mr. Nwaehiri submitted a reply to the Board's Notice of Intent to Revoke Pharmacist's License wherein he asserted that the Board lacked jurisdiction to determine whether or not his criminal conviction is valid pending its appeal. Mr. Nwaehiri also asserted that the Board lacked the "requisite judicial powers to determine [his] innocence." For these reasons, Mr. Nwaehiri, requested the Board "drop" its Notice of Intent to Revoke Pharmacist's License. (State's Ex. 4B). The Board considers Mr. Nwaehiri's reply a Motion to Dismiss.

The Board heard Mr. Nwaehiri's oral arguments on the Motion immediately prior to the evidentiary hearing. Mr. Nwaehiri provided no legal basis to support his claim that the Board lacks jurisdiction over this matter. The Board's jurisdiction over its licensees is plainly set forth in the Maryland Pharmacy Act. Maryland Code, Health Occ., § 12-313(b)(22) provides that the Board may discipline a licensee, including revoking his pharmacist license, if the licensee "[i]s convicted of ... a felony ..., whether or not any appeal or other proceeding is pending to have the conviction or plea set aside." "Conviction" is defined in Health Occ., § 12-313(a) to include "a determination of guilty, a guilty plea, or a plea of nolo contendere followed by a sentence." Mr. Nwaehiri had ample opportunity during his 31 day criminal trial to present to the jury all of the evidence he presented to the Board. While it is not within the Board's jurisdiction or purview to review the validity of Mr. Nwaehiri's criminal convictions, it is certainly within the Board's jurisdiction to sanction his pharmacist's license based upon the judgment of a competent court. Mr. Nwaehiri's contention that the Board lacks jurisdiction in this matter is without merit.

Mr. Nwaehiri's reliance upon <u>Clay v. United States</u>, 537 U.S. 522 (2003) and <u>Heck v. Humphrey</u>, 512 U.S. 477 (1994) for his assertion that the Board must await the determination of his criminal appeal before proceeding against his pharmacist license is misplaced. Whether finality has attached to Mr. Nwaehiri's criminal conviction for the purpose of his criminal appeal or any post-conviction collateral attack is an entirely different issue than whether the Board has jurisdiction to proceed with disciplinary action against his license based on such conviction.

In fact, the U.S. District Court for the District of Maryland denied the request for injunction Mr. Nwaehiri filed on December 14, 2009, in which he sought to enjoin the Board from taking action against his pharmacist license pending appeal of his criminal convictions. The Honorable Benson Everett Legg found that Mr. Nwaehiri cannot meet the standard for injunctive relief set forth in Winter v. Natural Resources Defense Council, Inc., --U.S. --, 129 S.Ct. 365, 374-376 (2008). The Court stated:

Plaintiff cannot show he is likely to succeed on the merits of his [administrative] claim. The pending appeal of his conviction has no bearing on the issue of license revocation. See Md. Health Occup., Code Ann. § 12-313(b)(22). He is also unlikely to suffer irreparable harm if the Board is not enjoined as he will have available to him state court appellate proceedings to review the merits of the Board's decision. See Md. Rule 7-201 et seq. Finally, the public interest would not be well served if the Board were enjoined from enforcing its own state licensing provisions prohibiting the licensure of convicted felons who are serving a term of incarceration.

Nwaehiri v. Maryland State Bd. of Pharm., Civil Action No. L-09-3358 (Jan. 6, 2010).

The Board hereby denies Mr. Nwaehiri's request to dismiss its Notice of Intent to Revoke Mr. Nwaehiri's Pharmacist's License.

## FINDINGS OF FACT

Based upon the testimony and documentary evidence presented at the hearing, the Board finds that the following facts are true:

- 1. At all times relevant to the charges giving rise to this action Mr. Callixtus Nwaehiri, the Respondent, was licensed to practice pharmacy in Maryland under License Number 10899.<sup>4</sup> (State's Ex. 1).
- 2. At all times relevant hereto, Mr. Nwaehiri and Mr. Sodipo owned and/or operated NewCare Home Health Services, Inc. ("NewCare"), located at 3423-2425 Sinclair Lane, P.O. Box 4118, Baltimore, MD 21213, which held permits authorizing NewCare to operate a pharmacy and distribute prescription drugs in the State of Maryland.
- 3. On November 8, 2006, the Board issued an Order of Summary Suspension to Mr. Nwaehiri, pursuant to Md. St. Gov't Code § 10-226(c)(2) (2004 Repl Vol.), based, in pertinent part, on the following:
  - a. An inspector from the Maryland Division of Drug Control ("DDC") inspected NewCare in December 2005. The DDC inspector was informed by the Respondent that NewCare was not conducting any internet pharmacy business. The DDC inspector was also provided with a list of Long-Term Care facilities served by NewCare. It was later discovered that some of the facilities on that list were not actually Long-Term Care facilities, and many did not have the number of beds as stated on the list. (State's Ex. 2A).

<sup>&</sup>lt;sup>4</sup> Mr. Nwaehiri allowed his license to lapse in November, 2007.

- b. Information from the United States Drug Enforcement Administration ("DEA") revealed the following:
  - i. In 2003, NewCare purchased approximately 4,200 dosage units of Hydrocodone<sup>5</sup> for further distribution. In 2004, NewCare's orders of Hydrocodone rose to 4,600 dosage units. In 2005, NewCare ordered in excess of four million dosage units of Hydrocodone. As of August, 2006, NewCare had ordered in excess of four million tablets of Hydrocodone, making NewCare the number one purchaser of Hydrocodone of all pharmacies in the State of Maryland. In comparison, the second largest purchaser of Hydrocodone in Maryland had purchased approximately 162,800 dosage units of Hydrocodone in the same timeframe in 2006. (State's Ex. 2A).
  - ii. NewCare was distributing Hydrocodone to various locations around the United States via internet sales. "Patients" were able to obtain Hydrocodone from NewCare by accessing an internet website, furnishing cursory information, medical records, and paying for a phone consultation. An individual then contacted the "patients" for a consultation; however, no physical exams were conducted. The physicians issuing the prescriptions were not located in Maryland, and the "patients" receiving the prescriptions were located all over the United States. (State's Ex. 2A).

<sup>&</sup>lt;sup>5</sup> Hydrocodone is a Schedule III Controlled Substance.

- iii. Some of NewCare's Long-Term Care facilities were in fact local residences incapable of holding the stated number of beds listed in NewCare's facility listing. (State's Ex. 2A).
- iv. On or about June 21, 2006, federal agents conducted a trash search of refuse removed from a dumpster used by NewCare. The following items were discovered:
  - Approximately 250 empty 500-ct. Hydrocodone containers (7.5/500 mg, 7.5/700 mg, 10/500 mg, 10/650 mg, all marked "Watson"). (State's Ex. 2A).
  - 2. Approximately 1,362 prescription labels were discovered in NewCare's trash.<sup>6</sup> Of those prescriptions, approximately 1,225 were for combination Hydrocodone products, totaling 113,907 tablets. Each label was marked with the heading "Prescription." Each label contained an ID number, process date, and shipping date. Each label also contained patient names, addresses, phone numbers, dates of birth, allergies, specific medication and dose, directions for use, and the physician's name, DEA number, address, and phone number. A large *electronic* signature<sup>7</sup> of the

<sup>&</sup>lt;sup>6</sup> Code Md. Regs. Tit. 10, § 34.05.04A(1) states that "A pharmacy permit holder shall: (1) prevent unauthorized disclosure or loss by securing all patient records[.]"

<sup>&</sup>lt;sup>7</sup> Code Md. Regs. Tit. 10, § 19.03.09A(1) states that "A pharmacist may dispense directly a controlled dangerous substance listed in Schedules III, IV, or V, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, or State Law, only pursuant to either a written prescription signed by a prescribing individual practitioner or a facsimile received by facsimile equipment of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy or pursuant to an oral prescription made by a prescribing individual practitioner and immediately reduced to writing by the

- doctor is visible in the center portion of the page on each label. The labels also had markings indicating that they were internet orders. (Emphasis added). (State's Ex. 2A).
- 3. The prescription labels were for prescriptions filled on May 18, 2006, June 1, 7, 12, 14, 15, 16, 19, and 20, 2006. The majority of the prescriptions were filled on June 15 (523), June 16 (233), June 19 (287), and June 20 (293). The labels identified customers in 47 states and the District of Columbia. Eight physicians were identified as the prescribers for all the "patients." None of the physicians listed on the labels were Maryland physicians. The majority were located in Florida. (State's Ex. 2A).
- v. On or about October 10, 2006, a DDC inspector accompanied members of various federal agencies to NewCare's pharmacy. The DDC inspector observed federal agents interviewing various employees and federal agents conducting an inventory and seizing NewCare's CDS inventory. Federal agents arrested Mr. Nwaehiri and Mr. Sodipo. (State's Ex. 2A).
- c. Pursuant to a federal indictment, Mr.Nwaehiri and Mr. Sodipo, among others, were charged with two counts:

## Count One:

did knowingly, intentionally, and unlawfully combine, conspire, confederate, and agree with each other and with other known and unknown to the Grand Jury to distribute and possess with intent to

pharmacist containing all information required in Regulation .07 of the chapter, except the signature of the prescribing individual practitioner."

distribute, outside the scope of professional practice and not for a legitimate medical purpose, a controlled substance, that is, at least eight (8) million dosage units of hydrocodone, a Schedule III controlled substance, in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(D).

## Count Two:

did knowingly, intentionally, and unlawfully, combine, conspire, confederate, and agree with each other and with others known and unknown to the Grand Jury to commit the following offenses against the United States, in violation of Title 18, United States Code, Section 1956(a)(1):

to conduct and attempt to conduct financial transactions affecting interstate commerce that involved the proceeds of specified unlawful activities in connection with the distribution of hydrocodone, a Schedule III controlled substance, in violation of Title 21, United States Code, Sections 841 and 846, knowing that the funds involved in the financial transactions represented the proceeds of the specified unlawful activities, and with the intent to promote the carrying on of the specified unlawful activities, as set forth in Count One of this Indictment, in violation of Title 18, United States Code, Section 1956(a)(1)(A)(1); and knowing that the transactions were designed in whole or in part to conceal or disguise the nature, the location, the source, the ownership, or the control of the proceeds of the specified unlawful activities, as set forth in Count One of this Indictment, in violation of Title 18, United States Code, Section 1956(a)(1)(B)(I). (State's Ex. 2A).

The federal indictment also included a provision governing the forfeiture to the United States of property belonging to Mr. Nwaehiri and/or NewCare. Specifically enumerated in the Indictment was the "property known as NewCare Pharmacy, and NewCare Home Health Services, Inc., located at 3423-25 Sinclair Lane, Baltimore City, Maryland," bank accounts, vehicles, and personal residences, among other things. The assets seized equaled approximately \$20 million in alleged illegal drug sales. (State's Ex. 2A).

- 4. The Board held a Show Cause on November 29, 2006 to determine whether to continue the Summary Suspension. (State's Ex. 2B).
- 5. On January 5, 2007, the Board issued Mr. Nwaehiri an Order Continuing Summary Suspension based upon the information outlined above in #3. The Board stated the following in its Order:

[Mr. Nwaehiri] has been federally indicted for dispensing, not for a legitimate medical purpose, at least 8 million dosage units of Hydrocodone, a Schedule III controlled dangerous substance in less than two years. The Board finds that it is nearly impossible to justify dispensing such an excessive number of any controlled substance within such a short time period. In fact, it appears that [Mr. Nwaehiri], along with his pharmacist business partner, was forced to create false long-term care facility clients in order to justify the purchasing of Hydrocodone in such large quantities.

In addition to the enormous quantities of controlled substances, the "patients" were located throughout the United States, and it appears that most of the prescribing physicians were in states other than the home state of the patient. It is, therefore, very difficult for the Board to accept that [Mr. Nwaehiri] believed that an actual physician-patient relationship truly existed in order to validate the millions of prescriptions for controlled substances.

The federal court order prohibits [Mr. Nwaehiri] from dispensing narcotics unless the Board grants approval. The Board, through this Order, is denying such approval. Furthermore, the Board finds there is a substantial likelihood that [Mr. Nwaehiri] would pose a risk to the public health, safety and welfare if [Mr. Nwaehiri] was permitted to dispense any prescription drugs, as even certain non-controlled substances have significant street value.

(State's Ex. 2B).

6. The Order Continuing Summary Suspension provided Mr. Nwaehiri with notice of an opportunity for an evidentiary hearing on the summary suspension. (State's Ex. 2B). No request for a hearing was made, nor did Mr. Nwaehiri otherwise contest the findings of the Order.

- 7. On July 31, 2008, after a 31 day jury trial, Mr. Nwaehiri was convicted in the United States District Court for the District of Maryland on counts of conspiracy to distribute controlled substances; aiding and abetting distribution of controlled substances; aiding and abetting conspiracy to launder monetary instruments; completing monetary transactions with criminally derived proceeds; and filing false tax returns. (State's Ex. 3).
- 8. On or about December 20, 2008, Mr. Nwaehiri was sentenced to five years incarceration, followed by three years of probation. An \$11.8 million judgment was issued against Mr. Nwaehiri and Mr. Sodipo. (State's Ex. 3).
- 9. Mr. Nwaehiri is currently appealing his criminal convictions.

#### CONCLUSIONS OF LAW

Based upon the foregoing summary of evidence, findings of fact, and opinion, the Board concludes that Mr. Nwaehiri is subject to discipline pursuant to Md. Code, Health Occ., § 12-313(b)(22).

#### OPINION AND SANCTION

The Board's primary duty is protection of the public. Md. Code, Health Occ. § 12-205. To that end, the Board has the authority to revoke the license of a licensee who has been criminally convicted. Health Occ. § 12-313(b)(22). It is undisputed that Mr. Nwaehiri has been criminally convicted of distributing controlled dangerous substances (i.e. eight million doses of Hydrocodone), aiding and abetting the distribution of controlled substances; aiding and abetting a conspiracy to launder monetary instruments;

completing monetary transactions with criminally derived proceeds; and filing false tax returns. (State's Ex. 3).

Given the serious nature of Mr. Nwaehiri's convictions and the fact that these acts were committed during his operation of a pharmacy, revocation is appropriate. Mr. Nwaehiri blatantly disregarded the law and is currently serving a five-year prison sentence as a result of his convictions. Mr. Nwaehiri's assertions that the Board should conduct its own investigation are absurd given the fact that a seven-week jury trial heard all of the evidence he and his attorney presented and found him guilty beyond a reasonable doubt nonetheless. Mr. Nwaehiri was using his pharmacist license purely for monetary gain and the illegal distribution of Schedule II drugs despite knowing that they are the most addictive substances, the dispensing of which should be subjected to heightened scrutiny. While it is difficult to assess the exact extent of harm Mr. Nwaehiri caused those patients who illegally received massive quantities of Schedule II drugs from his pharmacy, it is reasonable to conclude that some may have formed addictions to these habit-forming medications or suffered serious side effects.

Further, Mr. Nwaehiri also ignored the importance of verifying a doctor/patient relationship before dispensing extremely large quantities of controlled substances. (Tr. at 52). Instead, Mr. Nwaehiri routinely filled prescriptions for large quantities of Hydrocodone issued by Florida doctors (or doctors in other states) for patients outside of the state. Florida's Standards for Telemedicine Prescribing Practice and the Federation of State Medical Boards' Model Guidelines for the Appropriate Use of the Internet in Medical Practice, upon which Mr. Nwaehiri relies in support of his innocence, both pointedly cautions prescribers from using online medical questionnaires as the basis for

dispensing drugs. Fla. Admin. Code Ann. r. 64B8-9.014(1) (2003). (Resp. Ex. 3, 5). In fact, it provides that a physician shall not issue a prescription without, among other things, a documented patient evaluation. Fla. Admin. Code Ann. r. 64B8-9.014(2)(a). (Resp. Ex. 3). It is difficult for the Board to imagine that Mr. Nwaehiri verified the doctor-patient relationship in each instance where a Florida doctor was prescribing to an out-of-state patient in order to ensure his compliance with 21 C.F.R. § 1306.04 (Purpose and Issuance of a Prescription). (Resp. Ex. 7-8).

Although Mr. Nwaehiri argued that the law is not clear and that the Board had not provided him with direction regarding his practice (Tr. at 50), the Board warned all licensees in its April 2005 newsletter and subsequent clarification that "[p]harmacists may expose themselves to potential disciplinary actions if they fill multiple prescriptions through Internet services for patients if it is obvious that a physician-patient relationship does not exist." (Resp. Ex. 7-8). The Board also questions the validity of the "sample" prescription from Dr. Stanley Mark Dratler which Mr. Nwaehiri admitted into evidence. (Resp. Ex. 2). The prescription is not dated, and the number of refills used and remaining is unclear.

Finally, Mr. Nwaehiri showed no remorse for his criminal behavior. Rather, he made it clear that his operation of NewCare Pharmacy was based on any perceived "gray area" in the law which he could find. (Tr. at 49; Resp. Ex. 4). The Board finds inexcusable such a cavalier attitude toward criminal conduct that amounted to the illegal dispensing and distribution of mass quantities of highly addictive controlled substances. As a licensed healthcare professional, Mr. Nwaehiri had an obligation to protect the public by avoiding such activities.

## **ORDER**

Based upon the foregoing Findings of Fact, Conclusions of Law, and Opinion, by a unanimous decision of the Board, it is hereby:

**ORDERED** that the Mr. Nwaehiri's pharmacist license is REVOKED; and be it further,

**ORDERED** that the Board shall entertain a Petition for Reinstatement should Mr. Nwaehiri's criminal convictions in *United States v. Callixtus Nwaehiri*, Case No. L-06-0444, are overturned in their entirety, and be it further,

ORDERED that this is a final order of the Board and as such is a PUBLIC DOCUMENT pursuant to Md. Code, State Gov't, § 10-611, et seq.

 $\frac{4/14/2010}{\text{Date}}$ 

Donald Taylor, P.D.

President, Board of Pharmacy

#### NOTICE OF RIGHT TO APPEAL

Pursuant to Md. Code, Health Occ., § 12-316, you have the right to take a direct judicial appeal. A petition for appeal shall be filed within thirty (30) days from the date of mailing of this Final Decision and Order and shall be made as provided for judicial review of a final decision in the Maryland Administrative Procedure Act, Md. Code, State Gov't, § 10-201, et seq. and Title 7, Chapter 200 of the Maryland Rules.